UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* CHANDRU CHANDRASEKARAN

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Appeal No. 2006-0959
Application No. 10/075,914
Technology Center 3700

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Decided: August 31, 2006

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Before GARRIS, WALTZ, and TIMM, Administrative Patent Judges.

TIMM, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims 1-27, which are all of the claims pending in this application. We have jurisdiction over the appeal pursuant to 35 U.S.C. § 134.

## INTRODUCTION

The claims are directed to an intraluminal stent comprising a metallic reinforcing component and a biodegradable polymeric material covering at least a portion of the metallic reinforcing component (Specification, ¶ 0010, ll. 2-3). Intraluminal stents, according to the specification, "are typically inserted or implanted into a body lumen, for example, a coronary artery, after a procedure such as percutaneous transluminal coronary angioplasty ("PCTA")." (Specification, ¶ 0002, ll. 1-3). Further according to the specification, "[s]uch stents are used to maintain the patency of the coronary artery by supporting the arterial walls and preventing abrupt reclosure or collapse thereof which can occur after PCTA." (Specification, ¶ 0002, ll. 3-5).

Claim 1 illustrates the invention on appeal:

1. An intraluminal stent comprising:

> a metallic reinforcing component; and
>
> a biodegradeable polymeric material covering at least a portion of the metallic reinforcing component;
>
> the metallic reinforcing component providing structural reinforcement for the stent but being insufficient, in the absence of biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

The Examiner rejects the claims under both 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a). The Examiner relies on the following prior art references as evidence of unpatentability:

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|---|---|---|
| Ragheb | US 5,824,049 | Oct. 20, 1998 |
| Wolff | US 5,725,567 | Mar. 10, 1998 |
| Mayer | US 5,630,840 | May 20, 1997 |

The rejections as presented by the Examiner are as follows:[1]

A. Claims 1-10, 13, 15, 18, 20-22, 25 and 27 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Ragheb.[2]

B. Claims 1, 5-10, 12, 13, and 14 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Wolff.

C. Claims 2 and 11 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over the combination of Wolff and Mayer.

D. Claims 14, 16, 17, 19, 23, 24, and 26 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over the combination of Ragheb and Wolff.

## OPINION

As no claim is argued separately from any other and because the section 103 rejections are not separately argued, for each rejection we select claim 1 to represent the issues on appeal. We affirm substantially for the

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[1] The Examiner withdrew the rejection of claims 14 and 16 under 35 U.S.C. § 112, ¶ 2 (Answer, p. 2).

[2] The listing of "2-22" in the Answer instead of "20-22" is harmless error as evidenced by the Final Rejection and Brief.

reasons advanced by the Examiner and provide the following discussion primarily for emphasis.

**A. Rejection under 35 USC § 102(b)**

The Examiner maintains two grounds of rejection over 35 U.S.C. § 102(b). We discuss each separately as follows.

**1. Rejection of claims 1-10, 13, 15, 18, 20-22, 25, and 27 over Ragheb.**

In rejecting claims 1-10, 13, 15, 18, 20-22, 25, and 27 over Ragheb, the Examiner finds that Ragheb describes an intraluminal stent including a biodegradable polymeric material covering a metallic reinforcing component as required by the first two clauses of claim 1. With respect to the third clause of claim 1, the Examiner interprets this clause as encompassing the stent of Ragheb because neither "[t]he specification nor the claims provide specific structural limitations that distinguish the claimed invention from the prior art." (Answer, p. 7). The Examiner provides two reasons why the language is not particularly limiting on the structure of the stent: (1) the sufficiency of the metallic reinforcing component in providing structural reinforcement is dependent on many factors including the size and shape of the lumen into which it is implanted; and (2) because the phrase "maintaining patency" encompasses maintaining the stent open by preventing endothelial cell growth or accumulation debris in the lumen as well as by preventing collapse of the stent structure (*Id.*).

Appellant does not dispute that, as found by the Examiner, Ragheb describes an intraluminal stent including a metallic reinforcing component covered by a biodegradable polymeric material as required by the first two clauses of claim 1. In fact, Appellant acknowledges that such stents were

known in the prior art (Brief, p. 6). What Appellant argues is that "[t]he concept of the invention, in which a polymeric coating is used to provide structural support to a metallic stent that would otherwise not have sufficient strength to maintain patency of a lumen upon implantation of the stent into the lumen, however, is not in the prior art and is not disclosed in Ragheb." (*Id.*). According to Appellant, Ragheb uses the biodegradable polymer coating to deliver therapeutic agents, not to provide structural support *(Id.)*.

The problem is that claim 1 does not require that the polymeric coating provide structural support nor does it distinguish the structure of the claimed stent from that of Ragheb. Claim 1 simply states that "the metallic reinforcing component [provides] structural reinforcement for the stent but [is] insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen." The first portion of the clause requires that the metallic reinforcing component provide structural reinforcement. There is no question that the metallic component of Ragheb provides such reinforcement. The second portion of the clause requires that the metallic reinforcing component be "insufficient to provide a stent capable of maintaining patency." The word(s) "strength" or "insufficient strength" is(are) not used here. Nor does "maintaining patency" equate to maintaining patency through structural reinforcement. As used in the biological sciences, "patency" simply means the state or quality of being open, expanded, or unblocked. See "patency" at dictionary.com citing, among others, The American Heritage Stedman's Medical Dictionary. As found by the Examiner, patency can be maintained by preventing endothelial cell growth or accumulation of debris in the lumen as well as by using structural

reinforcement to prevent collapse.

Our review of the specification uncovers no disclaimer or disavowal of the ordinary and customary meaning of the term "patency." In fact, the use of the term in Appellant's specification is consistent with the ordinary and customary meaning. *In re Paulsen,* 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994)("An inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.'"). Our reviewing court counsels us that the PTO should avoid the temptation to limit broad claim terms solely on the basis of specification passages and tells us that, absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification when those sources expressly disclaim the broader definition. *In re Bigio,* 381 F.3d 1320, 1324-25, 72 USPQ2d 1209, 1210-11 (Fed. Cir. 2004). During prosecution, Appellant is free to amend the claims to include language carrying a narrower meaning. "As an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris,* 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1026-1028 (Fed. Cir. 1997). We, therefore, determine that "maintaining patency" encompasses maintaining the stent open, expanded, and unblocked by any method including by preventing endothelial cell growth or accumulation of debris in the lumen. Ragheb discloses that blockages due to restenosis and occlusion occur due to the stent implantation as further found by the Examiner

(Answer, p. 7; Ragheb, col. 1, ll. 18-37).

In the reply brief, Appellant further argues that "the appealed claims require that the metallic component of the stent be insufficient to maintain patency of the lumen 'upon implantation,' not after the passage of time." (Reply Brief, p. 4). We do not agree that "upon implantation" as it is used in the claim suffices to distinguish the claimed stent from the stent of Ragheb. The phrase can be read, in the context of the clause as a whole, as indicating patency is maintained once the stent is implanted, the phrase does not require prevention of immediate blockage. The combined phrase, "maintaining patency upon implantation" may mean both keeping the lumen open by mechanical structure of a stent immediately after the implantation, or by preventing restenosis over time. Furthermore, Ragheb describes preventing abrupt closure due to thrombosis which through the use of the polymeric coating layers also meets the claim limitation (Rageheb, col. 1, l. 62 to col. 2, l. 8 and col. 5, ll. 52-59).

Even if we were to accept Appellant's narrow interpretation of "insufficient ... of maintaining patency. . . upon implantation" as limited to immediate mechanical collapse, we agree with the Examiner that the claim is not particularly limited in terms of stent structure in a way that differs from the prior art. As cogently articulated in the Answer, "[t]here are no specific amounts, ratios, or dimensions provided for any of the stent materials that distinguish the claimed invention from prior art stents." Stent and lumen sizes vary as do the forces on the stents at the particular locations in the body. As stated in Ragheb, "[s]tructures such as stents or catheter portions intended to be used [at sites other than coronary arteries] such as in the aorta, esophagus, trachea, colon, biliary tract, or urinary tract will have

different dimensions more suited to such use." (Ragheb, col. 7, ll. 3-11). Therefore, depending on where the stent is placed, the metallic stent may very well be insufficient to maintain patency of the lumen. The problem again is one of claim breath. The language of the claim does not limit the structure of the metallic reinforcing component to any particular dimensions and, therefore, does not distinguish the claimed stent structure from the structure of the prior art. While Appellant argues that the Examiner's rejection is based on a theory of inherency, the true issue here is one of claim breath.

Lastly, we note that the question here is not whether Ragheb teaches the "concept of the invention" as put by Appellant. It is whether Ragheb describes what is claimed when the claim terms are given their broadest reasonable interpretation as they would be understood by one of ordinary skill in the art reading the specification. "[T]he name of the game is the claim." *In re Hiniker Co.,* 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998).

We conclude that the Examiner has established a prima facie case of anticipation with respect to the subject matter of claims 1-10, 13, 15, 18, 20-22, 25, and 27 which has not been sufficiently rebutted by Appellant.

**2. Rejection of claims 1, 5-10, 12, 13, and 14 over Wolff.**

To reject claims 1, 5-10, 12, 13, and 14, the Examiner also relied upon Wolff as evidence of anticipation. Appellant states that many of the arguments directed to the rejection over Ragheb are relevant to Wolff. For reasons analogous to those discussed above, we do not find those arguments persuasive.

Appellant further points out that the Examiner at one point relies upon Figure 14 of Wolff and its description at column 7, lines 18-22 as showing bonding of the metallic component to the polymeric component. Appellant argues that Figure 14 actually represents bonding of individual strands of metal to each other and points to column 7, lines 26-27. We cannot agree that Figure 14 is directed to bonding of strands of metal. Figures 12-15 depict various weaves for the stents of Figures 1 and 2. Figure 1 depicts a "purely polymeric prosthesis" (Wolff, col. 9, ll. 35-37) shown in cross-section in Figure 3A (Wolff, col. 2, ll. 48-49). Figure 14 represents bonding of strands (filaments 12) made of polymer, not metal (Wolff, col. 9, ll. 1-11).

Moreover, even if Wolff described bonding metal filaments in Figure 14, the other portions of Wolff relied upon by the Examiner support the Examiner's finding of anticipation.

**B. Rejection under 35 U.S.C. § 103 (a)**

The Examiner maintains two grounds of rejection, as discussed below:

**1. Rejection of claims 2 and 11 over Wolff in combination with Mayer.**

To reject claims 2 and 11, the Examiner added Mayer as further evidence of obviousness. There being no new argument over and above what we have already addressed, we conclude that the Examiner has established a prima facie case of unpatentability with respect to the subject matter of claims 2 and 11 that has not been contested by Appellant.

**2. Rejection of claims 14, 16, 17, 19, 23, 24, and 26 over Ragheb in combination with Wolff.**

To reject claims 14, 16, 17, 19, 23, 24 and 26, the Examiner added Mayer as further evidence of obviousness. There being no new argument

over and above what we have already discussed, we conclude that the Examiner has established a prima facie case of unpatentability with respect to the subject matter of claims 2 and 11 that has not been contested by Appellant.

## CONCLUSION

Based upon a review of the totality of the evidence of record with due consideration of the arguments advanced by the Appellant, we conclude that a preponderance of the evidence supports a finding of anticipation within the meaning of 35 U.S.C. § 102 (b) and a conclusion of obviousness within the meaning of 35 U.S.C. § 103(a). We therefore affirm the Examiner's rejections.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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